Complete Summary

GUIDELINE TITLE

Colorectal cancer screening clinical practice guideline.

BIBLIOGRAPHIC SOURCE(S)

Kaiser Permanente Care Management Institute. Colorectal cancer screening clinical practice guideline. Oakland (CA): Kaiser Permanente Care Management Institute; 2008 Dec. 190 p. [195 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Kaiser Permanente Care Management Institute. Colorectal cancer screening clinical practice guideline. Oakland (CA): Kaiser Permanente Care Management Institute; 2006 Nov. 74 p. [96 references]

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Colorectal cancer

GUIDELINE CATEGORY

Prevention
Risk Assessment
Screening

CLINICAL SPECIALTY

Family Practice
Gastroenterology
Internal Medicine
Obstetrics and Gynecology
Oncology
Preventive Medicine

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Health Care Providers
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

- To assist primary care and specialist physicians and other health care professionals in counseling asymptomatic adults who are at increased risk for colorectal cancer about appropriate screening procedures
- To assist physicians, administrators, and other health care professionals from Kaiser Permanente in determining the most effective medical practices for colorectal cancer screening

TARGET POPULATION

Asymptomatic adults aged 18 and older at average or increased risk of colorectal cancer

Note: This guideline addresses colorectal cancer screening in the general, asymptomatic adult population seen in the primary care setting. It does not address screening and/or surveillance in adults with a personal history of colorectal cancer or inflammatory bowel disease, or a family history of hereditary colorectal cancer syndromes, such as familial adenomatous polyposis, Gardner's syndrome, and hereditary nonpolyposis colon cancer (Lynch syndrome).

INTERVENTIONS AND PRACTICES CONSIDERED

1. Risk assessment
    - Family history
    - Consideration of age, race, ethnicity in risk assessment
2. Screening of asymptomatic adults using one of the following:
    - Immunochemical fecal occult blood test (iFOBT/FIT)
    - Flexible sigmoidoscopy
    - High-sensitivity fecal occult blood test (FOBT)
    - Combined high-sensitivity guaiac FOBT and flexible sigmoidoscopy
    - Colonoscopy
3. Consideration of frequency of colorectal cancer screening
4. Consideration of age to begin and end colorectal cancer screening
5. Screening of adults at increased risk of colorectal cancer

Note: The following tests were considered but not recommended: air-contrast barium enema, virtual colonoscopy, and fecal DNA.

MAJOR OUTCOMES CONSIDERED

- Incidence of colorectal cancer (i.e., predictive value of prognostic factors)
- Morbidity and mortality from colorectal cancer
- Adverse effects of tests
- Sensitivity and specificity of tests

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Guidelines are developed using an "evidence-based methodology" that involves a systematic literature search, critical appraisal of the research design and statistical results of relevant studies, and grading of the sufficiency (quantity, quality, consistency, and relevancy) of the evidence for drawing conclusions.

During the guideline development process, the Guideline Development Team reviews evidence published in peer-reviewed scientific journals, existing evidence-based guidelines, and consensus statements from external professional societies and government health organizations, and clinical expert opinion of Kaiser Permanente regional specialty groups.

For details of the literature search, including databases searched and search terms for each clinical question, see the original guideline document.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Refer to Table 2 in the Appendix of the original guideline document for the system for grading the strength of a body of evidence.

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

The Guideline Development Team performed systematic reviews of the medical literature on each of the clinical questions identified by the workgroup.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

To develop a guideline, the Kaiser Permanente Care Management Institute (CMI) consultants work with a multidisciplinary team of physicians and other health care professionals. This Guideline Development Team (GDT) consists of a core multidisciplinary group of physicians representing the medical specialties most affected by the guideline topic, and other content experts from disciplines such as pharmacy, nursing, and social work, as appropriate. The members of the GDT are endorsed by the National Guideline Directors from their region.

During the guideline development process, the GDT reviews evidence published in peer-reviewed scientific journals, existing evidence-based guidelines, consensus-based statements from external professional societies and government health organizations, and clinical expert opinion of Kaiser Permanente regional specialty groups. The members of the GDT develop the guideline and facilitate the information exchange in both directions on behalf of the Region that they represent. This process should include obtaining the buy-in of the local champions regarding the guideline so that it will be implemented once published.

To update the Colorectal Cancer Screening Guideline, released in November 2006, a multidisciplinary, interregional Guideline Development Team (GDT) first met in June 2008 to define the scope of the guideline. The Project Management Team then performed systematic reviews of the medical literature on each of the clinical questions identified by the GDT, assembled the evidence, and developed draft recommendations for review by the GDT. All of the recommendations and supporting evidence were reviewed by the GDT in depth through a series of conference calls in September and October 2008.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Recommendations are classified as either "evidence-based (A-D, I)" or "consensus-based."

- *Evidence-based*: Sufficient number of high-quality studies from which to draw a conclusion, and the recommended practice is consistent with the findings of the evidence. A recommendation can also be considered "evidence-based" if there is insufficient evidence and no practice is recommended.
- *Consensus-based*: Insufficient evidence and a practice is recommended based on the consensus or expert opinion of the Guideline Development Team.

Label and Language of Recommendations

Label	Evidence-Based Recommendations*
Evidence-based (A)	**Language**: [a] The intervention is strongly recommended for eligible patients. **Evidence**: The intervention improves important health outcomes, based on good evidence, and the Guideline Development Team (GDT) concludes that benefits substantially outweigh harms and costs. **Evidence Grade**: Good.
Evidence-based (B)	**Language**: [a] The intervention is recommended for eligible patients. **Evidence**: The intervention improves important health outcomes, based on 1) good evidence that benefits outweigh harms and costs; or 2) fair evidence that benefits substantially outweigh harms and costs. **Evidence Grade**: Good or Fair.
Evidence-based (C)	**Language**: [a] No recommendation for or against routine provision of the intervention. (At the discretion of the GDT, the recommendation may use the language "option," but must list all the equivalent options.) **Evidence**: Evidence is sufficient to determine the benefits, harms, and costs of an intervention, and there is at least fair evidence that the intervention improves important health outcomes. But the GDT concludes that the balance of the benefits, harms, and costs is too close to justify a general recommendation. **Evidence Grade**: Good or Fair.
Evidence-based (D)	**Language**: [a] Recommendation against routinely providing the intervention to eligible patients. **Evidence**: The GDT found at least fair evidence that the intervention is ineffective, or that harms or costs outweigh benefits. **Evidence Grade**: Good or Fair.
Evidence-based (I)	**Language**: [a] The evidence is insufficient to recommend for or against routinely providing the intervention. (At the discretion of the GDT, the recommendation may use the language "option," but must list all the equivalent options.) **Evidence**: Evidence that the intervention is effective is lacking, of poor quality, or conflicting and the balance of benefits, harms, and costs cannot be determined. **Evidence Grade**: Insufficient.
Consensus-based	**Language**: [a] The language of the recommendation is at the discretion of the GDT, subject to approval by the National Guideline Directors.

Label	Evidence-Based Recommendations*
	Evidence: The level of evidence is assumed to be "Insufficient" unless otherwise stated. However, do not use the A, B, C, D, or I labels which are only intended to be used for evidence-based recommendations. **Evidence Grade**: Insufficient, unless otherwise stated.
For the rare consensus-based recommendations which have "Good" or "Fair" evidence, the evidence must support a different recommendation, because if the evidence were good or fair, the recommendation would usually be evidence-based. In this kind of consensus-based recommendation, the evidence grade should point this out (e.g., "Evidence Grade: Good, supporting a different recommendation").	

[a] All statements specify the population for which the recommendation is intended.

*Recommendations should be labeled and given an evidence grade. The evidence grade should appear in the rationale. Evidence is graded with respect to the degree it supports the specific clinical recommendation. For example, there may be good evidence that Drugs 1 and 2 are effective for Condition A, but no evidence that Drug 1 is more effective than Drug 2. If the recommendation is to use either Drug 1 or 2, the evidence is good. If the recommendation is to use Drug 1 in preference to Drug 2, the evidence is insufficient.

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The National Guideline Directors' Quality Committee reviewed and sponsored the guideline in November 2008. All recommendations included in the guideline were approved by the National Guideline Directors.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Definitions of the levels of evidence (evidence-based A-D, I and consensus-based) are provided at the end of the "Major Recommendations" field.

Recommendation 1*: Factors Associated with an Increased Risk of Colorectal Cancer in the General Population

A. A significant family history is associated with an increased risk of colorectal cancer. (*See Recommendation #5, below, for screening recommendations and specific definition of family history*.) (**Evidence-based: A**)
B. Advancing age is associated with an increased risk of colorectal cancer.** (**Evidence-based: B**)
C. There is fair evidence that blacks are at increased risk for colorectal cancer compared with whites. (**Evidence-based: C**)
D. There is fair evidence that a family history of advanced adenomas (i.e., ≥10 mm, with villous features or high-grade dysplasia) presenting before age 60 is associated with an increased risk of colorectal cancer. (**Evidence-based: C**)
E. There is insufficient evidence for or against the association of gender with an increased risk of colorectal cancer. (**Evidence-based: I**)

*The Guideline Development Team (GDT)Â adopted a hazard ratio >2.0 as the cut-point to declare a risk factor as sufficient to warrant a screening recommendation different from that for people at average risk.

**Indirect evidence from analyses using cancer registry, Medicare, and other surveillance data indicates that the risk of cancer and advanced colonic neoplasms increases with age.

Recommendation 2: Effectiveness of Colorectal Cancer Screening Tests

A. Colorectal cancer screening is strongly recommended for all asymptomatic, average-risk adults. (**Evidence-based: A**)
B. Any of the following tests are acceptable for colorectal cancer screening in asymptomatic, average-risk adults:*
    - High-sensitivity fecal occult blood test (FOBT) (**Consensus-based**)
    - Immunochemical fecal occult blood test (iFOBT/FIT)** (**Consensus-based**)
    - Flexible sigmoidoscopy (**Evidence-based: B**)
    - Colonoscopy** (**Consensus-based**)
    - A combination of high-sensitivity guaiac FOBT test and flexible sigmoidoscopy (**Consensus-based**)
C. The following additional screening tests are either less-preferred options or not recommended for screening.Â However, an adult who has had one of these tests is considered screened. Follow-up screening using a preferred option is recommended.
    - An annual standard guaiac FOBT is a less-preferred option.*** (**Consensus-based**)
    - Air contrast barium enema is not recommended as a screening strategy for average-risk adults. (**Evidence-based: I**)
    - Virtual colonoscopy is not recommended as a screening strategy for average-risk adults.* (**Consensus-based**)
    - Fecal DNA is not recommended as a screening strategy for average-risk adults.****(**Consensus-based**)

Note: For fecal blood tests, inform patients of the potential risks associated with false-positive test and false-negative test results, as well as the need for prompt follow-up of a positive test result.Â For flexible sigmoidoscopy, inform patients that the test has a small risk of complications and is not a complete examination of the entire colon.

*There is insufficient evidence to choose one screening test over another.

**If a patient has had a normal colonoscopy within the last 10 years, there is insufficient evidence that supplemental FOBT adds any incremental benefit.

***Even though there is sufficient evidence in support of this screening modality, it is not a preferred option due to its low sensitivity and low compliance rates.

****Please note that fecal DNA testing and virtual colonoscopy are not listed as "appropriate screening tests" in 2008 HEDIS (Health Plan Employer Data and Information Set) specifications for colorectal cancer screening, and therefore regions may choose to screen members with other appropriate tests.

Recommendation 3: Frequency of Colorectal Cancer Screening

A. The following intervals for colorectal cancer screening in asymptomatic, average-risk adults are recommended*:
    - Flexible sigmoidoscopy: at least every 10 years (**Consensus-based**)
    - High-sensitivity guaiac or immunochemical FOBT (iFOBT/FIT): every 1-2 years (**Consensus-based**)
    - Colonoscopy: every 10 years (**Consensus-based**)
    - Combined FOBT and flexible sigmoidoscopy: every 1-2 years for FOBT, at least every 10 years for flexible sigmoidoscopy (**Consensus-based)**
B. The following additional screening tests are either less-preferred options or not recommended for screening. However, if these tests are performed, then the recommended intervals are as indicated below. Follow-up screening using a preferred option is recommended.
    - Standard guaiac FOBT: every 1-2 years (**Consensus-based**)
    - Air contrast barium enema:** every 5 years (**Consensus-based**)
    - Virtual colonoscopy:** every 10 years (**Consensus-based**)
    - Fecal DNA:** every 5 years (**Consensus-based**)

* The GDT recognizes that these screening intervals differ from current HEDIS measures.Â Some regions may choose to offer screening at more frequent intervals.Â HEDIS intervals are as follows: FOBT (annual), flexible sigmoidoscopy (every 5 years), air contrast barium enema (every 5 years), colonoscopy (every 10 years).

**These modalities are not recommended for screening average-risk adults (see Recommendation #2 above).

Recommendation 4: Age to Begin and End Colorectal Cancer Screening

In the absence of sufficient evidence, the following ages at which to begin and end colorectal cancer screening in asymptomatic average-risk adults are recommended:

A. Initiation of screening is recommended at age 50. (**Consensus-based**)
B. Discontinuation of screening is generally recommended at age 75, provided that there is a history of routine screening. For those with no history of routine screening, discontinuation is recommended at age 80. The decision to discontinue screening should be based on physician judgment, patient preference, the increased risk of complications in older adults, and existing comorbidities. (**Consensus-based**)

Recommendation 5: Screening in Adults at Increased Risk of Colorectal Cancer

Family History

Colonoscopy screening beginning at age 40, or 10 years younger than the earliest diagnosis in the first-degree relative, is recommended in adults with the following significant family history of colorectal cancer:

- One first-degree relative (parent, sibling, or offspring) with a diagnosis of colorectal cancer at age 60 or younger* (**Consensus-based**)
- Two or more first-degree relatives diagnosed with colorectal cancer at any age* (**Consensus-based**)

A. For adults with a family history of advanced adenomas (>10 mm, or with villous features or high-grade dysplasia) presenting before age 60, colonoscopy screening beginning at age 50, at least every 10 years, may be the preferred option. (**Consensus-based**)
B. For adults with a family history of advanced adenomas (≥10 mm, or with villous features or high-grade dysplasia) presenting before age 60, colonoscopy screening beginning at age 50 may be a preferred option. (**Consensus-based**)
C. For evaluation and follow-up of hereditary colorectal cancer syndromes and inflammatory bowel disease, referral to Gastroenterology is recommended.** (**Consensus-based**)

*There is fair evidence that a family history of advanced adenomas presenting before age 60 is associated with an increased risk of adenomas or colorectal cancer. (**Evidence-based: C)**

**Hereditary syndromes include familial adenomatous polyposis (FAP), Gardner's syndrome, and hereditary nonpolyposis colon cancer (HNPCC or Lynch syndrome).

For blacks, special efforts should be made to ensure that screening occurs using any of the accepted screening modalities, as well as consideration of earlier screening as compared with other racial groups.Â Observational national data demonstrate an increased risk of colorectal cancer and a more advanced stage of disease at diagnosis among blacks than among whites. It is not clear whether this disparity is due to differences in the biological behavior of colorectal cancer in blacks, differences in socioeconomic status, or differences in access to care.

Women are at slightly lower risk than men for colorectal cancer, at the same age. However, this risk difference is not significant enough to justify a different approach to colorectal cancer screening for men and women.

Age, Race or Ethnicity, and Gender

D. Special efforts are recommended to ensure screening in adults aged 60-75, using any of the accepted screening modalities.Â If colonoscopy is used for screening in adults without a family history of colorectal cancer, it is most likely to be beneficial for fit adults aged 60-75, where the incidence of proximal cancers is higher and the balance of benefits vs. harms is favorable. Because colonoscopy requires procedural sedation and vigorous bowel preparation and has a higher rate of complications than other tests, counseling on the benefits and risks of screening is recommended, especially in older adults with comorbidities. (**Consensus-based**)
E. Special efforts are recommended to ensure that screening occurs among blacks, using any of the accepted screening modalities. (**Consensus-based**)

F. There is insufficient evidence to recommend for or against differential screening strategies based on gender. (**Evidence-based: I**)

Definitions:

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CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is not specifically stated for each recommendation, but the evidence underlying the recommendations are drawn

from randomized controlled trials, meta-analyses, and existing systematic reviews. In cases where the data was inconclusive, inconsistent, or non-existent, recommendations were based on the consensus opinion of the group.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Appropriate colorectal cancer screening
- Early detection of colorectal cancer in the general population; asymptomatic, average-risk adults; and increased-risk adults
- Reduced morbidity and mortality from colorectal cancer

POTENTIAL HARMS

- Inconvenience, anxiety, and adverse effects of tests (e.g., discomfort, pain, bowel perforation, bleeding)
- Unnecessary invasive tests due to false-positive test results
- False reassurance from false-negative test results

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- These guidelines are informational only. They are not intended or designed as a substitute for the reasonable exercise of independent clinical judgment by practitioners, considering each patient's needs on an individual basis.
- Guideline recommendations apply to populations of patients. Clinical judgment is necessary to design treatment plans for individual patients.
- This guideline addresses colorectal cancer screening recommendations in the general, asymptomatic adult population seen in the primary care setting. It does not address screening and/or surveillance in adults with a personal history of colorectal cancer or inflammatory bowel disease, or a family history of hereditary colorectal cancer syndromes, such as familial adenomatous polyposis (FAP), Gardner's syndrome, and hereditary nonpolyposis colon cancer (HNPCC or Lynch syndrome).

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2006 Nov (revised 2008 Dec)

GUIDELINE DEVELOPER(S)

Kaiser Permanente Care Management Institute - Managed Care Organization

SOURCE(S) OF FUNDING

Kaiser Permanente Care Management Institute

GUIDELINE COMMITTEE

Colorectal Cancer Screening Guideline Project Management Team

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Team Members: Theodore R. Levin, MD, Clinical Lead, KP-Northern California; Betina Pereira, Project Manager, KP-Mid-Atlantic States; Yerado Abrahamian, MHS, Lead Analyst, KP-Southern California; Jill Haynes, MPH, Analyst, KP-Program Office; Marguerite A. Koster, MA, MFT, Team Leader, TAG Unit, KP-Southern California; Stephanie Goldman, MPH, Analyst, KP-Southern California; Wiley Chan, MD, EBM Methodologist, KP-Northwest; Gladys Tom, Senior Manager, Knowledge Services, KP-Program Office; Tabitha Pousson, Staff Assistant, KP-Program Office

Colorectal Cancer Screening Guideline Development Team (GDT): Colorado: Craig Robbins, MD – EBM Director; Karin Kempe – Director of Clinical Prevention; Tom Matzakos, MD – Gastroenterology; William Rector, MD – Gastroenterology. Georgia: Rodney Harris, MD – Quality Management. Hawaii: Robert Decker, MD – Gastroenterology; Theresa Dizon, MD – Gastroenterology. Mid-Atlantic States: Bradley Winston, MD – Gastroenterology. Northern California: Theodore R. Levin,

MD – Gastroenterology. Northwest: Elizabeth Liles, MD – Gastroenterology; Wiley Chan, MD – EBM Methodologist. Ohio: Cathy Kortyka, RN – Gastroenterology. Oregon EPC: Evelyn Whitlock, MD – USPSTF Improvement, Permanente Federation. Program Office: Jed Weissberg, MD – Assoc. Executive Director, Quality & Performance. Southern California: Daniel S. Anderson, MD – Gastroenterology; Stanford Gertler, MD – Gastroenterology

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

No members stated any conflicts of interest.

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Kaiser Permanente Care Management Institute. Colorectal cancer screening clinical practice guideline. Oakland (CA): Kaiser Permanente Care Management Institute; 2006 Nov. 74 p. [96 references]

GUIDELINE AVAILABILITY

Electronic copies: None available

Print copies: Available from the Kaiser Permanente Care Management Institute, One Kaiser Plaza, 16th Floor, Oakland, CA 94612

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI Institute on July 9, 2007. The information was verified by the guideline developer on August 3, 2007. This NGC summary was updated by ECRI Institute on September 14, 2009.

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